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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/717,883	11/21/2000	Susana Salceda	DEX-0115	2018

26259 7590 02/26/2002

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EXAMINER

DAVIS, NATALIE A

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 02/26/2002

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/717,883

Applicant(s)

SALCEDA ET AL.

Examiner

Natalie A. Davis

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 December 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3-7 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Applicant's amendment filed 12 December 2001 (Paper No: 12) is acknowledged. Accordingly, claim 3 is amended and claims 3-7 are pending.

Information Disclosure Statement

The information disclosure has been considered. A signed copy is attached hereto.

Applicant's traversal of the election of Group III, claims 3-7 is acknowledged. The traversal is on the ground(s) that the inventions are not independent and distinct and may be examined without a serious burden because art relating to Group III should reveal art relating to the other Groups. This is not found persuasive for reasons indicated in the previous office action, as the Groups have different class/subclass, thus rendering them independent and distinct and a serious burden to search.

The requirement is still deemed proper and is therefore made FINAL. Claims 3-7 are being examined as belonging to the elected Group III, while claims 1-2 and 8-16 are withdrawn from examination as being drawn to a non-elected invention.

Response to Arguments

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Specification Objection - Maintained

1. Objection to the abstract of disclosure is maintained. Applicant did not send a marked version and therefore, amendments to the abstract have not been entered.

Claim Rejections - 35 USC § 112 1st Withdrawn

2. Rejection of claims 3-7 under 35 U.S.C.112, first paragraph is withdrawn in view of arguments and amendments to the claims.

New Claim Rejection - 35 USC § 112 1st

3. Claims 3-7 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for diagnosis comprising determining an increase in Ovr107 nucleic acid levels, does not reasonably provide enablement for diagnosis comprising determining an increase in Ovr107 levels other than nucleic acid levels. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

4. The specification indicates that Ovr107 refers to "among other things native proteins expressed by the gene comprising the polynucleotide sequence of SEQ ID NO: 1" (p. 2). The claims are broadly drawn to measuring Ovr107 levels, which includes proteins and polynucleotides and applicant is only enabled for determining BCSG levels using nucleic acid based assays, wherein the mRNA is measured because the specification has not give any guidance or exemplification that Ovr107 protein is expressed and determining protein expressions levels is indicative of diagnoses, staging, and monitoring. Thus, it would be an undue burden to one of ordinary skill in the art to assay for BCSG levels beyond using nucleic acid based assays because applicant has not shown that the BCSG protein is expressed and increased expression levels are indicative of a breast cancer diagnosis.

5. An article by Alberts, et al. is cited in order to establish the general state of the art and the level of predictability of protein translation. Those of skill in the art, recognize that expression of mRNA does not dictate the translation of such mRNA into a polypeptide. Alberts, et al. (Molecular Biology of the Cell, 3rd edition, 1994, page 465) teach that translation of ferritin mRNA into ferritin polypeptide is blocked during periods of iron starvation. Likewise, if excess iron is available, the transferrin receptor mRNA is degraded and no transferrin receptor polypeptide is translated. Many other proteins are regulated at the translational level rather than the transcriptional level. Thus, predictability of protein translation is not necessarily contingent on mRNA expression due to the multitude of homeostatic factors affecting transcription and translation. Therefore, one of skill in the art would not be able to predict if the nucleic acids of BCSG were in fact translated into protein. One cannot extrapolate the teachings of the specification to the scope of the claims because the claims are broadly drawn to determining BCSG levels. Accordingly, it would be an undue burden and unpredictable for one of ordinary

Art Unit: 1642

skill in the art to assay Ovr107 protein levels. The claims may be allowable if they were to recite "determining levels of Ovr107 mRNA or polynucleotide" or some other language that is supported by the specification, which indicates polynucleotide levels are determined.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalie A. Davis whose telephone number is 703-308-6410. The examiner can normally be reached on M-F 8-5:30 (every other Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa PhD can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4315 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Natalie Davis, PhD
February 20, 2002



**GEETHA P. BANSAL
PRIMARY EXAMINER**